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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,866	05/29/2001	Brian Sorrentino	1340-1-021 CIP2	4688

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EXAMINER

LI, QIAN J

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,866

Applicant(s)

SORRENTINO ET AL.

Examiner

Q. Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group VI, claims 16, and 17, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that all of the claims relate to the identification of stem cells using antibodies that bind to BCRP, each of the claims contain the components for use in the same endpoint, and a search of literature relating to identification of stem cells would clearly reveal art relating to all the groups. Thus, the inclusion of all of the groups in this application would not be overly burdensome to the Examiner. The arguments have been fully considered but they are not persuasive because contrary to the assertion, not all the claims relate to the identification of stem cells using antibodies that bind to BCRP. For example, as indicated in paper# 10, group II is drawn to a method of identifying a stem cell or quantifying BCRP expression using nucleic acid probes to BCRP, which do not require the use of an antibody, group III is drawn to identifying a stem cell comprising detecting the BCRP expression by measuring the pumping activity of the cell, which do not require the use of the antibody, and group V is drawn to cells that do not require a search for the antibody. The antibody of group VI could be used in different processes such as for diagnostic assay as taught by Scheffer et al or could be used as in a therapeutic method such as taught by Casey et al, and the method of identifying a cell could be practiced with materially different substances such as, using a nucleic acid (group II) or a dye (group III). The search for different groups of invention is not co-extensive. M.P.E.P. states, "FOR PURPOSES OF THE

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INITIAL REQUIREMENT, A SERIOUS BURDEN ON THE EXAMINER MAY BE PRIMA FACIE SHOWN IF THE EXAMINER SHOWS BY APPROPRIATE EXPLANATION OF SEPARATE CLASSIFICATION, OR SEPARATE STATUS IN THE ART, OR A DIFFERENT FIELD OF SEARCH AS DEFINED IN MPEP § 808.02".

Therefore, it is maintained that each of the Inventions requires a separate search status and consideration. The inventions are mutually exclusive and independent products and processes. Therefore, it is maintained that these inventions are distinct due to their divergent subject matter. Further search of all groups would impose a severe burden to the Office. The requirement is still deemed proper and is therefore made **FINAL**.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 1-20 are pending, however, claims 1-15 and 18-20 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 16 and 17 are under current examination.

Priority

It is acknowledged that this application claims the benefit of priority to US application 09/584,586, filed 5/31/2000.

It is noted that this application also claims the benefit of priority over PCT/US99/11825 and U.S. provisional application 60/086,988. However, the applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119 and 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance ontracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

In the instant case, the subject matter of the elected invention, BCRP molecule has not been disclosed in PCT/US99/11825 and U.S. provisional application 60/086,988. Therefore, the priority date for this application has been established as 5/31/2000.

Applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims recite an antibody that recognizes an extracellular portion of a BCRP, wherein said extracellular portion of the BCRP is in its natural conformation. Because

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the recited antibody may be present naturally, e.g. in the serum of a patient suffering leukemia, or a recipient of allogenic stem cell transplantation, the claims read on the product of nature. Amending the claims to recite "an isolated antibody" would obviate this rejection.

Claim Objections

Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 17 depends from a claim (claim 16) drawn to an antibody that recognizes BCRP, wherein the recitation, "the BCRP is on the surface of a viable stem cell" further limits the BCRP, but not the antibody. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by *Scheffer et al* (Proc Am Assoc Cancer Res 2000 Mar;41:page 803).

The claims are drawn to an antibody that recognizes an extracellular portion of a BCRP, wherein said extracellular portion of the BCRP is in its natural conformation, wherein the BCRP is on the surface of a viable stem cell.

Scheffer et al teach a monoclonal antibody for detection of a BCRP protein in the cell membrane (surface) of the cells from MCF-7 sublines, i.e. an antibody recognizing the extracellular portion of the BCRP protein on the cell surface; and a BCRP would inherently be present on the surface of a viable stem cell, therefore, *Scheffer et al* anticipate the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Ross et al* (US 6,313,277, IDS/AA), in view of *Niman et al* (US 5,563,247).

Ross et al teach the BCRP protein is a novel xenobiotic transporter which is overexpressed in a variety of human cancer cells, (paragraph bridging columns 1 & 2), and states, "It is another objective of the invention to provide antibodies to the BCRP" (column 2, line 30). Since only the extracellular portion of the protein on the cell surface is accessible to antibody recognition, the antibody taught by *Ross et al* meets the claim limitation, i.e. recognizing the extracellular portion of the BCRP protein on the cell surface; and BCRP would inherently be present on the surface of a viable stem cell. *Ross et al* do not actually disclose an anti-BCRP antibody in the specification. However, at the time of the instant effective filing date, it is well known in the art how to make an antibody from a protein or polypeptide. For example, *Niman et al* teach the method of making antibody against the cell receptor polypeptides (abstract, claims 1-9).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the methods taught by *Niman et al* to make an antibody to BCRP as taught by *Ross et al* with a reasonable expectation of success. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
December 2, 2002

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

